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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,591	12/21/2001	Eugene Medlock	01017/37128C	6379

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,591	MEDLOCK ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *9, 12-56, and 60-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,11 and 57-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's election with traverse of Group I invention, claims 1-8, 10 and 11, directed to SEQ ID NO:1, in Paper No. 15, filed on 24 April 2003 is acknowledged. The traversal is on the ground(s) that the nucleic acid molecules of claims 57-59 in Group VIII are the same as that in Group I. This argument is persuasive, and the restriction requirement between Group I and Group VIII inventions is withdrawn.

In addition, applicants traverse the restriction requirement between Group I and Group II inventions on the ground(s) that it would not be a serious burden on the Examiner to do one search based on the claims in Groups I and II as Group I will involve the same prior art and identify similar art compared to a search based on the polypeptides of Group II. This is not found persuasive because the polypeptide can be made by alternative ways other than recombinant method, such as chemical synthesis, or isolation from its natural source. Therefore, a search of the polypeptide may not reveal the prior art of the corresponding nucleic acid. In addition, even though the polypeptide of Group II can be made by the process of Group I, a search of Group I invention may not provide useful information on the *use* of the polypeptide. As any search of the prior art in regard to group I may reveal whether any prior art exists as to the other Groups, a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a *separate* search of relevant literature in different areas of subject matter. As so, the separate searches for both groups constitute an undue burden to the Office.

The requirement is still deemed proper and is therefore made FINAL.

Further, applicants require to rejoin Groups I and XII as Group XII is directed to a method of using the nucleic acid (gene therapy) of Group I invention. Applicants argument of the decisions in *In re Ochiai* and *In re Brouwer* is noted but is not deemed persuasive, as PTO practice in view of those decisions is directed to rejoinder of claims after allowable subject matter has been indicated, and not to withdrawal of restriction requirements. Applicants are advised that at such time as the elected product claim(s) are indicated as being allowable, rejoinder of claims drawn to methods of using such may be requested under 35 U.S.C. §103(b)

pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86). Such rejoinder is *not* tantamount to a withdrawal of the restriction requirement.

Applicants arguments on the restriction requirement between Groups not involving Group I invention is moot as they are drawn to non-elected inventions.

Currently, claims 1-78 are pending, and claims 1-8, 10, 11 and 57-59 are under consideration. Claims 9, 12-56, and 60-78 are withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Priority

This application claims priority to US applications 09/868,404 and 09/810,384, and US provisional applications 60/213,125 and 60/266,159. For the following reasons, the Examiner finds that the present claims 1-8, 10, 11 and 57-59 are not supported in the manner required by 35 U.S.C. 101 and 112, first paragraph by the prior application 60/213,125, thus none of present claims is entitled to the benefit of the filing date of the prior application 60/213,125.

The priority application 60/213,125, filed on 22 June 2000, merely discloses one human and two murine polypeptide sequences having SEQ ID NO:2, 4 and 10, respectively, and indicates that they are IL-17 like polypeptides based on sequence similarity to known IL-17. The prior application 60/213,125 fails to provide any specific, substantial and credible utility for the claimed IL-17 like polypeptides, and provides no guidance or working examples to teach how to used the claimed invention. Therefore, the Examiner is not able to establish that the priority document 60/213,125 satisfies the utility/enablement requirement of 35 U.S.C. 101/112, first paragraph. As such, the claims of the instant application are not entitled to the benefit of the filling date of prior application 60/213,125. Priority is granted to the filing date of the later provisional application, 60/266,159, filed on 02 February 2001, wherein some specific and substantial biological properties of said IL-17 like polypeptides were disclosed, such as induction of TNF-α and IL-6 in cultured human T-lymphblast cells (Example 7).

Specification

The specification is objected to because the ATCC numbers at page 177, line 17, and page 179, line 6, for example, are left blank. Correction is required for all missing numbers throughout the specification.

Claims

Claims 1-3 are objected to for encompassing a non-elected subject matter, SEQ ID NO:3, 4, 9 or 10. The applicant is required to amend the claims to read only upon the elected invention.

Claim 11 is objected under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 is dependent from claim 2, which is drawn to an isolated nucleic acid. The additional limitation in claim 11 is directed to a computer program, which does not further limit the nucleic acid in the independent claim 2.

Double Patenting Rejections:

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8, 10, 11 and 57-59 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8, 10, 11 and 57-59 of copending Application No. 09/886,404. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10, 11 and 57-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are incomplete for omitting essential elements. Part (c) of claim 1, part (e) of claim 2, and part (g) of claim 3 are limited by a hybridization method under moderate or high stringency conditions. However, the claims recite neither hybridization conditions to ensure that any hybridized polynucleotides will comprise specific sequence within the meaning of the disclosure, nor process steps which would effect the removal of nonspecific hybridization complexes. Examples of "highly stringent" and "moderately stringent" conditions are noted in the specification (page 33, lines 9-26, and page 35, lines 1-12). However, examples of such fall within the intended definition, and are not considered, in themselves, to provide definitive conditions for the hybridization. Without a clear delineation of hybridization conditions, one can not determine the metes and bounds of nucleic acids within the limitations of the claim. The claims are further indefinite for the recitation of "an activity". It is unclear what activity is intended, and the specification does not define such, therefore, the metes and bounds of the claims cannot be unambiguously determined.

Claim 2 is further indefinite for reciting "at least about 70, 75, ... or 99 percent identical to" in part (a). As all of "75 ... or 99 percent" are embraced by "at least about 70%", it is unclear why higher percents are listed since the lowest % is the only pertinent limitation.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and the dependent claims 4-8, 10, 11 and 57-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited

in scope to a nucleic acid of SEQ ID NO:1 encoding a polypeptide of SEQ ID NO:2, does not reasonably provide enablement for claims to various variants and fragments of SEQ ID NO:1 or of a nucleotide sequence encoding SEQ ID NO:2, such as hybridization variants thereof under moderately stringent conditions (claim 1, part (c), claim 2, part (e), and claim 3, part (g), for example), variants at least about 70% identical thereto (claim 2, part (a), for example), allelic or splice variants of SEQ ID NO:1 (claim 2, part (b), for example), fragments of SEQ ID NO:1 or encoding SEQ ID NO:2 (claim 2, parts (c) and (d), for example), and variants with substitution, deletion, insertion, or truncation (claim 3, for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 1-8, 10, 11 and 57-59 encompass various variants of SEQ ID NO:1 and nucleic acids encoding SEQ ID NO:2 (for example, hybridization variants, % variants, allelic and splice variants, and those of as listed above), and small fragments thereof. The specification discloses merely *one* nucleic acid of SEQ ID NO:1 encoding a human IL-17 like polypeptide (IL-17LP) having SEQ ID NO:2, and capable of inducing TNF-α and IL-6 in cultured human T-lymphoblast cells (Example 9). Further, The specification provides neither information about the structural and functional relationship within the claimed sequence (SEQ ID NO:2) as to which regions of the claimed polypeptides would be tolerant of modification and which would not regarding to retaining the functional activities of the polypeptide, nor guidance or working example of polypeptide variants less than 100% identical to SEQ ID NO:2 to teach a commensurate number of the claimed species. As the requirement for sequence identity for the % variants is relatively low (70%), it is less predictable that any randomly selected variant 70% identical to SEQ ID NO:2 would be functional. Therefore, in the absence of guidance, or working example, it is not reasonable to predict that a variant with 70% sequence identity to residues SEQ ID NO:2 would retain the functional activity.

With respect to the hybridization variants of said nucleotides, the claims read on any or all nucleotides hybridizing to SEQ ID NO:1 or to those encoding SEQ ID NO:2, and encoding a polypeptide sharing one activity with SEQ ID NO:2. It is well known in the art that hybridization will occur even under stringent conditions if there is only local identity between two molecules whose sequences might be totally divergent outside of that region. Such hybridized molecules may encode proteins capable of inducing TNF-α or IL-6, yet have other distinct biological functions from those of SEQ ID NO:2. The specification does not define a specific hybridization condition for obtaining the claimed species, or working examples of any such variants, which would be within the limitations of the claims. Therefore, it would require undue experimentation in order to make the claimed invention in its full scope.

With respect to the small nucleotide fragments encoding 25 amino acid residues of SEQ ID NO:2, and those having 16 nucleotides, given the fact that the IL-17LP polypeptide of the present invention has 161 amino acids, a randomly selected fragment of 25 amino acids is highly unlikely to possess the desired biological activity. As so, it would require undue experimentation to practice the invention in a manner commensurate in scope with the claims. Additionally, one of skill in the art would not know how to use a randomly selected nucleic acid sequence of 16 nucleotides of SEQ ID NO:1 or those encoding SEQ ID NO:2.

With respect to the variants in claim 3, without upper limit as to how many amino acids can be subject to the modifications, the claim reads on functional equivalents, which may have distinct sequence and other functional properties. For the similar reasons addressed above (for hybridization variants), it would require undue experimentation in order to make the claimed invention in its full scope.

Due to the large quantity of experimentation necessary to determine an activity the variants or fragments, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the lack of predictability that a fragment of 25 amino acids would be functional, and the breadth of the claims which embrace a broad class of structurally diverse variants and fragments, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim 1-8, 10, 11 and 57-59 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to various variants of SEQ ID NO:1 and nucleic acids encoding SEQ ID NO:2 (for example, allelic and splice variants, and those of % variants, as listed above). The specification discloses the nucleic acid of SEQ ID NO:1. No other variants of SEQ ID NO:1 meeting the limitations of these claims were ever identified or particularly described. The skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acid of SEQ ID NO:1 or those encoding the amino acid sequence of SEQ ID NO:2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. This is particularly important in absence of a specified activity, such as induction of TNF-α or IL-6. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 11 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Marra et al. for locus W88186 (EST, 12 September 1996).

Marra discloses a polynucleotide, locus W88186 comprising a fragment of nucleotides 609-631 of SEQ ID NO:1 of the instant invention with 100% sequence identity (see appended computer printout of sequence search results). The cited sequence anticipates claims 1-3 as being a nucleotide sequence hybridizing under moderately stringent conditions to SEQ ID NO:1 (claim 1, part (c), claim 2, part (e), claim 3, part (g)); a fragment of the nucleotide sequence of SEQ ID NO:1, and having at least 16 nucleotides thereof (claim 2 part (d), and claim 3, part (f)); a nucleotide sequence encoding a polypeptide of SEQ ID NO:2, which has a C- and/or N-terminal truncation, or at least one modification (claim 3, parts (d) and (e)), as the claims do not specify "an activity" and hybridization conditions, and/or no upper limit as to the sequence modifications and maximum size of the truncation (claim 3, part (d)). Additionally, the reference teaches a vector, pT7T3D-Pac, containing the cited nucleic acid sequence, and the vector was propagated in a DH10B host cell, the reference, therefore, also anticipates claims 4, 5, 7 of the instant application. With respect to claim 11, which depends from claim 2, the limitation of using computer to calculate the percent sequence identity does not alter the nature of the nucleic acid, and therefore, adds no patentable weight to said nucleic acid. Accordingly, the reference also anticipates claim 11. Although the reference does not explicitly teach a composition of said nucleic acid molecule with a pharmaceutically acceptable formulation agent, however, it is well known in the art that a purified nucleic acid is usually used in combination with other agent(s), such as dissolving solutions, and cannot be used as its solid form alone. Dissolving solutions, such as water, buffers, or media, meet the limitation of being "a pharmaceutically acceptable formulation agent". Therefore, the reference anticipates claim 57.

Claims 1-8, 10, 11 and 57-59 are rejected under 35 U.S.C. 102(a) as being anticipated by Gorman et al, WO200042187.

Gorman discloses a polynucleotide of SEQ ID NO:21 comprising nucleotides 140-644 of SEQ ID NO:1 of the instant invention with 99.8% sequence similarity, and encoding a human IL-174 having SEQ ID NO:22, which is 100% identical to SEQ ID NO:2 of the present invention (see computer printout of the search results). The reference, therefore, anticipates claims 1-3. Additionally, Gorman teaches a vector, including viral vectors and expression vectors (page 37, lines 14-15, and 17-17-19), comprising the cited nucleic acid sequence, and [non-native promoter DNA operatively linked to the nucleic acid sequence encoding said polypeptide (page 36, the second and third paragraphs), a eukaryotic or prokaryotic host cell containing said vector (page 38, the second paragraph), and a process of producing said polypeptide (page 35, "IV" to page 40). Therefore, the reference anticipates claims 4-8, 10, and 59. Furthermore, the reference anticipates claims 11, 57 and 58 for the same reasons above.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Marra et al. discloses a polynucleotide, locus AI430337 (EST, 15 March 2000), comprising nucleotides 251-644 of SEQ ID NO:1 of the instant invention with 84.5% sequence identity (see appended computer printout of sequence search results).

Lee et al. discloses a polynucleotide, locus AF305200 (GenEmbl, 09 January 2001), comprising nucleotides 165-644 of SEQ ID NO:1 of the instant invention with 99.8% sequence identity, and encoding a polypeptide of human IL-17E, which has amino acids 3-161 of SEQ ID NO:2 of the instant invention with 100% sequence identity (see appended computer printout of sequence search results).

Conclusion:

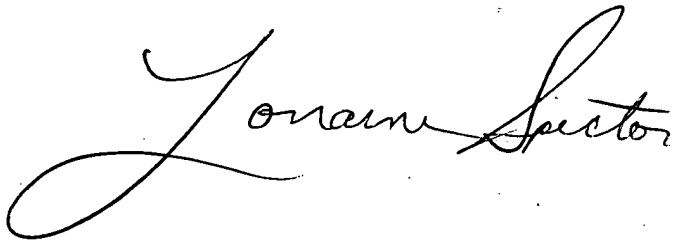
No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
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6/3/03